

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Wave 2 Cases Identified in the
Exhibit Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Larry T. Sirls, M.D.)

Pending before the court is the Motion to Exclude the General Opinion and Testimony of Larry T. Sirls, II, M.D. [ECF No. 2479] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 60,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 206, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels’ expectations that I align with

¹ On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 2, could not be identified because of an error in the style or case number, or assigned to another District Judge.

these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to “respect[] the individuality” of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court’s rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties’ *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess “whether the reasoning or methodology underlying the testimony is scientifically valid” and “whether that reasoning or methodology properly can be applied to the facts in issue.” *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a “reversal” of these decisions and is instead the expected result of the parties’ submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is

impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert

testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to

exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues.

Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's

clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony

where the party seeking exclusion does not provide specific content or context.

V. Remaining Issues

I **FIND** that the remaining issues contained in the plaintiffs' Motion are better suited for cross-examination. Accordingly, except as otherwise stated in this Memorandum Opinion & Order, the plaintiffs' Motion is **DENIED** in all other respects.

VI. Conclusion

The court **DENIES in part, GRANTS in part** and **RESERVES in part** the Motion to Exclude the General Opinion and Testimony of Larry T. Sirls, II, M.D. [ECF No. 2479].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 2 cases identified in the Exhibit attached hereto.

ENTER: March 29, 2017

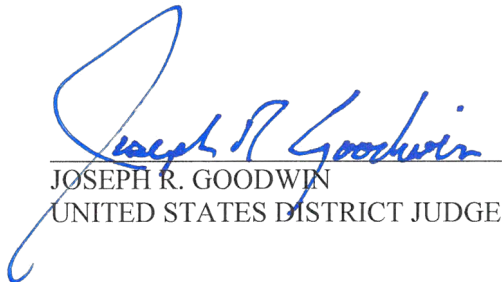

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case	Civil Action Number
Ankenman, Cathleen & John J.	2:12cv00872
Kowalski, Judith Mary	2:12cv01323
Hart, Mary Ann & William J.	2:12cv01326
Schroeder, Carreen & Matthew	2:12cv01327
Almendarez, Angela M.	2:12cv01329
Hines, Lynn & Gregory	2:12cv01331
Rose, Lola	2:12cv01336
Vandergriff, Debbie & Carl	2:12cv01342
Eaton, Cynthia & Frank	2:12cv01348
Aldrich, Jacqueline Marie & Darryl	2:12cv01364
Higgins, Susan & Bob	2:12cv01365
McDonald, Maria & Thomas	2:12cv01366
Glasgow, Carol	2:12cv01367
Valle, Maritza	2:12cv01368
Thomas, Mary	2:12cv01370
Fitzgerald, Alina & Christopher	2:12cv01371
Boudreau, Linda L. & Charles J.	2:12cv01373
Simpson, Sherry Gill & Ricky	2:12cv01414
Watson, Sandra Rosalie & Earl L.	2:12cv01426
Brady, Victoria Lee & Maurice Joseph	2:12cv01428
Mickle, Karen	2:12cv01432
Grayson, Pamela Sue	2:12cv01435
Pocztowski, Debra	2:12cv01470
Perry, Mary Lou	2:12cv01477
Ford, Deborah K. & Donald K. Blowers, Jr.	2:12cv01486
Brown, Valerie	2:12cv01489
Blackston, Ossie & John	2:12cv01493
Martin, Diann & Donald	2:12cv01495
Schomer, Margaret A.	2:12cv01497
Smith, Patricia G. & Mark	2:12cv01498
Cruse, Peggy D.	2:12cv01501
Raney, Barbara A. & Marcus	2:12cv01507
Espinoza, Rhondi	2:12cv01517
Majors, Jennifer A. & Jonathan S.	2:12cv01523
Flanigan, Iris & Earl David	2:12cv01524
Gologan, Didina & Alexandru	2:12cv01528
Burton, Kimberly Lee & Christopher Carl	2:12cv01529

Chase, Alvette	2:12cv01533
McGathey, Elizabeth M.	2:12cv01538
Ferguson, Teresa	2:12cv01544
Crews, Lillie Harriet & Wain E.	2:12cv01549
Spitzner, Bobbie Dianne & James W.	2:12cv01552
Sanders, Melissa & Charles, Jr.	2:12cv01562
Amidei, Betty	2:12cv01563
Childress, Sandra & Timothy	2:12cv01564
Cottrell, Teresa & Joe Palazzolo	2:12cv01565
Harper, Kathy	2:12cv01567
Wilson, Marcia & Robert	2:12cv01568
Rasos, Katherine	2:12cv01599
Walkingstick, Margaret Christine	2:12cv01616
Smythia, Rebecca	2:12cv01622
Smith, Andora	2:12cv01623
Lindberg, Patricia & Carl	2:12cv01637
Perez, Leezel & Jeffrey	2:12cv01640
Cole, Phyllis Smith & Willie Ray	2:12cv01645
Guffey, Gail	2:12cv01650
Hatfield, Nona & Billy Ray	2:12cv01657
Moore, Phyllis	2:12cv01659
Cooper, Jennifer & Dave	2:12cv01660
Carter, Tamara & David	2:12cv01661
Smallwood, Nancy & Leon, Sr.	2:12cv01662
Glenn, Rhonda & Era Fox, III	2:12cv01663
Allen, Diana & Timothy	2:12cv01676
Fleck, Jean E.	2:12cv01681
Lenz, Debera & Robert	2:12cv01692
Mooney, Konnie L. & James	2:12cv01695
Miller, Mona	2:12cv01696
Bailey, Pamela & Houston	2:12cv01700
Cedeno, Joyce	2:12cv01701
Colbert, Rhonda & Joseph	2:12cv01702
Hoch, Susan & Christopher	2:12cv01703
Johnson, Cynthia & Robert	2:12cv01704
Meyer, Linda & Steve	2:12cv01705
Muir, Marilyn & Scott	2:12cv01706
Shelton, Mary & Frank	2:12cv01707
Shennum, Janice	2:12cv01708
Swanson, Karen & Thomas	2:12cv01709
Parker, Belinda	2:12cv01710

Hutchison, Deanna Gail	2:12cv01711
Suter, Carol Ann & Troy W.	2:12cv01712
Denton, Shirley & Marvin	2:12cv01719
Frazier, Margaret & William Allen	2:12cv01731
Raines, Myra & Kenneth	2:12cv01735
Rhodes, Rebecca & Scott	2:12cv01736
Sidwell, Loretta & Jimmy	2:12cv01737
Williamson, Betty & Donald	2:12cv01739
Gibson, Susan & Michael	2:12cv01740
Savage, Stacey D. & Ebbie E. Ferrell	2:12cv01743
Blevins, Vickie Lea & Robert Oliver	2:12cv01746
Slade, Sebrina & Eric	2:12cv01753
Paris, Christin & Michael	2:12cv01759
Young, Tina L. & Jeffrey	2:12cv01772
Patrick, Lottie M. & John D.	2:12cv01776
Lane, Ann Jennette & Daniel Mark	2:12cv01785
Cutter, Jenesta & Larry A.	2:12cv01790
Burnett, Mary K.	2:12cv01795
Heuer, Myra	2:12-cv-01796
Hammett, Carolyn R.	2:12cv01802
Brookman, Lesley Mitchell & Michael	2:12cv01803
Merten, Janet & Gerard	2:12cv01817
Zutovsky, Linda & Leonard	2:12cv01818
Sierra, Ana & Luis	2:12cv01819
Hemingway, Veda & Gary	2:12cv01829
Strickland, Deborah J. & Matthew	2:12cv01830
Guy, Sheryl C.	2:12cv01831
Gray, Wanda	2:12cv01832
Abell, Emily S. & Michael K.	2:12cv01833
Bishop, Cheryl L.	2:12cv01834
Symank, Bernie & Herman	2:12cv01836
Franklin, Betty	2:12cv01837
Gallehugh, Michelle & Ronnie	2:12cv01838
Parton, Lori Anne Copeland, Executrix of the Estate of Sue Bilbrey Copeland, deceased	2:12cv01848
Peterson, Winnie Elise	2:12cv01849
Jernigan, Joan E. & Fred T.	2:12cv01850
Luna, Tracy L.	2:12cv01853
Hays, Brenda & Roger	2:12cv01855
Sutton, Martha	2:12cv01857
Hensley, Mary M.	2:12cv01858

Bowles, Phyllis & Charles	2:12cv01865
Rogers, Ruby G. & Dwayne L.	2:12cv01877
Irwin, Priscilla A. & Daniel S.	2:12cv01878
Dycus, Myrtle Frances	2:12cv01879
Henry, Lana & Phillip Dean	2:12cv01938
Garland, Marian	2:12cv01939
Young-Poole, Brenda	2:12cv01962
Riggs, Donna & Gary	2:12cv01967
Zapata, Sandra	2:12cv01972
Slocumb, Kathryn	2:12cv01974
Hughes, Brenda L. & Ronnie	2:12cv01976
Poole, Cheryl & Kenneth	2:12cv01978
Devoe, Debra & Randy	2:12cv01979
Moon, Carolyn	2:12cv01980
Covington-Branker, Barbara M. & Brian B.	2:12cv01983
Cope, Michele A. & Barry	2:12cv01984
De Forrest, Patricia Ann & John H.	2:12cv01985
Cambre, Terri I.	2:12cv01986
Trimper, Carolyn S.	2:12cv01987
West, Peggy Sue & Larry R.	2:12cv01988
Phillips, Eleanor F. & John R.	2:12cv01989
Higgins, Anna R.	2:12cv01990
Brennon, Rebecca J.	2:12cv01995
Carr, Gwendolyn N. & Rundell D.	2:12cv01996
Bates, Diane	2:12cv02020
Bowers, Betty Jean	2:12cv02022
Beard, Gavie & Kenneth	2:12cv02025
Carroll, Margaret	2:12cv02026
Gullett, Brenda & Carl	2:12cv02027
Maddox, Brenda	2:12cv02028
Martin, Phyllis	2:12cv02029
Peterson, Tracy & Kevin	2:12cv02030
Reed, Deborah F. & Dale K.	2:12cv02059
Chrysler, Marion	2:12cv02060
Heddle, Bridget	2:12cv02071
Pratt, Cathy	2:12cv02072
Hernandez, Toni	2:12cv02073
Dawson, Kristen	2:12cv02074
Daugherty, Angela & Jimmy	2:12cv02076
Marshall, Natalie C. & David R.	2:12cv02077
Hand, Wanda M. & Charles W.	2:12cv02079

Burns-Martin, Dayna & Kevin	2:12cv02081
Brady, Deborah D.	2:12-cv-02086
Hicks, Shannon H. & James D.	2:12cv02094
McClain, Barbara Sue	2:12cv02095
Roberts, Brenda C. & Dwight	2:12cv02096
Clay, Crystal Lynn	2:12cv02097
Wilson, Tina	2:12cv02099
Scott, Teresa	2:12cv02100
Bishop, Jessie	2:12cv02101
Whinery, Joyce	2:12cv02102
Nelson, Kathryn M.	2:12cv02103
Loomis, Barbara & Dighton	2:12cv02104
Minogue, Bridgette	2:12cv02112
Doucette, Karen L.	2:12cv02125
Dunham, Lynne & David	2:12cv02131
Ursini, Tara	2:12cv02132
Anderson, Elaine	2:12cv02134
Crabtree, Reba & Jack	2:12cv02135
Lary, Sheryl & Kevin E.	2:12cv02136
Manor, Kristy & John E., III	2:12cv02137
Maxwell, Bonnie	2:12cv02138
Lewis, Marlene	2:12cv02139
Messina, Laritza & John	2:12cv02140
Morrison, Laura	2:12cv02141
Panske-Phillips, Emma & Luther Y., Jr.	2:12cv02142
Phillips, Ramona	2:12cv02143
Pitts, Michelle	2:12cv02144
Green, Janice	2:12cv02148
Pippin, Laura & Donald	2:12cv02152
Bihlmeyer, Donna & Joe	2:12cv02159
Semere, Yvonne	2:12cv02160
Hreiz, Amy Elizabeth & Adel Elias	2:12cv02165
Villarreal, Katherine & Carlos	2:12cv02167
Ogletree, Linda J. & John A.	2:12cv02168
Partin, Patricia Graham	2:12cv02179
Pageau, Tina Marie	2:12cv02180
Lambert, Corrie Ann & Ronson	2:12cv02183
Martin, Patricia J. & Dennis R., Sr.	2:12cv02185
Miller, Rose M.	2:12cv02187
Pieper, Laura & Mike	2:12cv02189
Pridmore, Hope Elaine & James O.	2:12cv02190